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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,859	12/03/2001	Lee D. Arnold	BBC-059/A	9803

7590

02/03/2003

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EXAMINER

AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

18

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/831,859

Applicant(s)  
Arnold, L.D. et al.

Examiner  
CHARANJIT AULAKH

Art Unit  
1625



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov. 25, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-25, and 27-29 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-25, and 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

1. According to paper no. 17 filed on Nov. 25, 2002, the applicants have canceled claims 14 and 26 and furthermore, have amended claims 1, 11, 16 and 18. The applicants have also submitted an abstract.
2. Claims 1-13, 15-25 and 27-29 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments ( paper no. 17 ) with respect to claims 1-13, 15-25 and 27-29 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-13, 15-25 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting Vascular hyperpermeability using compound disclosed on page 33 of specification, does not reasonably provide enablement for all other known and unknown ( to be developed in future ) compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (

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see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988 ) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples and the state of the prior art.

The instant compound disclosed on page 33 selectively inhibits KDR tyrosine kinase ( see table on page 34 ) and more specifically catalytic responses of KDR/VEGFR-2 without affecting activity of Flt-1/VEGFR-1 and therefore, will have utility in treating vascular hyperpermeability.

The specification does teach various assays for testing activity of compounds for inhibiting cellular signaling function of KDR such as KDR tyrosine kinase activation or phosphorylation of KDR kinase substrates. However, the specification mentions only one representative compound with a definite structure which does show antagonist activity in various test assays. On the other hand, there are unlimited number of compounds ( in billions ) available in the prior art and to test every possible compound available in the prior art for antagonist activity in these assays, it would require undue experimentation to select compounds which inhibit cellular signaling function of KDR and hence inhibit vascular hyperpermeability.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-13, 15-25 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-13, 15-25 and 27-29, the term ----a compound that inhibits the cellular signaling function----- is indefinite since it is not clear which compound is being referred here. The applicants are suggested to include the structure of the compound in claims 1 and 16.

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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9. Claims 1-13, 15-25 and 27-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Arnold ( U.S. Patent no. 6,451,834 ).

Arnold discloses compounds of formula I ( see col. 5, lines 20-67 ) as inhibitors of tyrosine kinase activity having utility for inhibiting vascular hyperpermeability ( see col. 7, lines 4-51 ).

The compounds disclosed in col. 26 ( lines 40-60 ) and col. 28 ( lines 45-60 ) disclosed by Arnold clearly anticipate the instant claims.

10. Claims 1-13, 15-25 and 27-29 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Doyle ( U.S. Patent no. 6,297,238 ).

Doyle discloses compounds of formula I ( see col. 5, lines 20-67 ) as inhibitors of tyrosine kinase activity having utility for inhibiting vascular hyperpermeability ( see col. 18, lines 20-65 ). The compounds disclosed in claims 1-21 and a method of inhibiting protein kinase activity or vascular hyperpermeability using these compounds disclosed by Doyle clearly anticipate the instant claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on “ Monday-Thursday “ from 7:30 A.M. to 6:00 P.M.

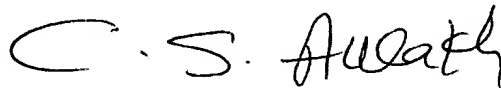
If the attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. Alan Rotman, can be reached on (703) 308-4698. The fax number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "C. S. Aulakh". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

CHARANJIT S. AULAKH

PRIMARY EXAMINER